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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,975	10/05/2005	Robert S. Meissner	20880P	3364

210 7590 02/20/2007  
MERCK AND CO., INC  
P O BOX 2000  
RAHWAY, NJ 07065-0907

EXAMINER
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RAMACHANDRAN, UMAMAHESWARI

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,975	MEISSNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Restriction/Election*

Applicant's election of group II claims 14-15 and the election of species 4-methyl-17 $\beta$ -[(4-trifluoromethylphenyl)acetamido]-4-aza-5 $\alpha$ -androst-1-ene-3-one in the reply filed on 12/18/2006 is acknowledged. The restriction election has been made with traverse. The applicant has stated in the restriction/election remarks that a search of the subject matters of Groups I and III in addition to the subject matter of Group II, would not be burdensome. Group I, claims 1-13, are drawn to method for modulating androgen receptor comprising administering a therapeutically effective amount of a compound of structural formula I (claim 1) and a bone-strengthening agent and Group III, claims 16-18 are drawn to a composition comprising a compound of structural formula I, a bone-strengthening agent and a pharmaceutically acceptable carrier. Group I is directed to a method of administering the compound along with a bone strengthening agent and Group III is directed towards composition comprising the compound of formula I along with the bone strengthening agent. The searches of Groups I - III may be overlapping but there is no reason to believe that the searches would be co-extensive. The examiner will be focusing on the patentability of the method and not on the composition or compound for the group I searches. Conversely, in searching Group II, the examiner will be focusing on the compound and not the method of treatment or composition. The search for all inventions would place an undue burden on the Office in view of the corresponding diversity in the field of search for each. Thus

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the restriction requirement elected is made final. Claims 1-13 and 16-18 are withdrawn from consideration. Claims 14 and 15 are pending.

The elected species is free of prior art. Hence the search was expanded to include other species in claims 14 and 15 and the following rejections have been made.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Witzel et al (U.S. 5,639,741).

Witzel et al. teaches a compound (compound 12 of claim 15 of the instant application) 4-methyl-17 $\beta$  -(2-fluorobenzamido)-4-aza-5 $\alpha$ -androst-1-ene-3-one (col. 18, line 9-10) and this addresses claims 14 and 15. The reference further teaches the following compounds: 17-(2,6-Difluorobenzamido)-4-methyl-5-.alpha.-4-azaandrost-3-one (col. 19, lines 1-2), 17-(2,3-Difluorobenzamido)-4,7-dimethyl-5-.alpha.-4-azaandrost-3-one (col.19, lines 37-38), 4-Methyl-17-(3-fluoro-2-methylbenzamido)-5.alpha.-4-azaandrost-3-one and 4-methyl-17 $\beta$  -(propamido)-4-aza-5 $\alpha$ -androst-1-ene-3-one.

**Conclusion**

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER